SRI TRANG GLOVES (THAILAND) PUBLIC COMPANY LIMITED Registration number 0107562000106

Heedquarter: No. 110, Kanjanevanit Road, Pahtong, Hat Yai, Songkhle 90230 Thailand Tel: (66) 74-471-471 Fax: (66) 74-291-650 Office: No. 10 Soi 10, Phetkasem Road, Hat Yai, Hat Yai, Songkhle 90110 Thailand Tel: (66) 74-344-663

Tel: (66) 74-344-663 Fax: (66) 74-344-677, 74-237-423, 74-237-832 บริษัท ศรีตรังโกลฟส์ (ประเทศไทย) จำกัด (มหาชน) ทะเบียนเลขที่ 0107562000106 สำนักงานใหญ่: เลขที่ 110 ถนนกาญจนวนิช ต่านลพะลง อำเภอหาคไหญ่ จังหวัดสงขลา 90230 ประเทศไทย เบอร์โทรศิพท์: 074-471-471 เบอร์โทรศิพท์: 074-471-471 เนอร์โทรศิพท์: 074-471-683 เบอร์โทรศิพท์: 074-344-683 เบอร์โพรศิพท์: 074-344-683, 074-237-423, 074-237-832



EU Declaration of Conformity to the 2017/745 Medical Device Regulation 2016/425 Personal Protective Equipment Regulation

We, Sri Trang Gloves (Thailand) Public Company Limited, declare under our sole responsibility that the medical device stated below meets all provisions of the Medical Device Regulation (EU) 2017/745 and Personal Protective Equipment Regulation (EU) 2016/425.

Manufacturer:	Sri Trang Gloves (Thailand) Public Company Limited
Address:	10 Soi 10, Phetkasem Road, Hat Yai, Songkhla 90110
	Thailand
Brand Name:	FAVORIT EDITION
Reference Number (REF):	XS size: REF 33006
	S size: REF 33007
	M size: REF 33008
	L size: REF 33009
	XL size: REF 33010
Product Name:	Latex Examination Gloves, Powder Free, Chlorinated,
	Non-Sterile, EU Spec, Medical Grade
Product Group Code:	LO01
Product Specification Code:	LOOOGF-B-WHT-EU-MC-NS
Intended Purpose:	A patient examination glove is a disposable device
	intended for medical purposes that is worn on the
	examiners hand or finger to prevent contamination
	between patient and examiner. Examination glove is
	intended for medical activities except surgery

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Fax: (66) 74-344-677, 74-237-423, 74-237-832

บริษัท ศรีตรังโกลฟส์ (ประเทศไทย) จำกัด (มหาชน)
 ทะเบียนเลขที่ 0107562000106
 สำนักงานใหญ่: เลขที่ 110 ถนนกาญจนอนิช ค่านลพะคง อำเภอหาคไหญ่
 จังหวัดสงงลา 90230 ประเทศไทย
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 เนอร์โทรศิพท์: 074-291-650
 สำนักงาน: เลขที่ 10 ชอย 10 ถนนเพชรเกษม ค่านลหาคไหญ่
 อำเภอหาคไหญ่ จังหวัดสงงลา 90110 ประเทศไทย
 แบอร์โทรศิพท์: 074-344-663
 แบอร์โทรศิพท์: 074-344-667, 074-237-433, 074-237-832



Device Classification: (As per MDR 2017/745)	Class I under Rule 1 and 5 according to Annex VIII
Basic UDI-DI:	88591306LO01V9
CE marking first applied:	May 2020
GMDN code and term:	47172 Hevea-latex examination/treatment glove, non-
	powdered, non-antimicrobial
EMDN/CND:	T010201 (Examination/ Treatment Gloves, Latex)
Conformity Assessment Route: (As per MDR 2017/745)	Annexes II and III

EC Representative for Sri Trang Gloves (Thailand) Public Company Limited is Medical Device Safety Service GmbH. Schiffgraben 41, 30175 Hannover, Germany

This Declaration of Conformity is issued on the basis of fulfilment the requirements of Annex IV of the Medical Device Regulation (EU) 2017/745 with:

- Quality Management System certification to EN ISO 13485: 2016 under the supervision of TÜV SÜD PRODUCT SERVICE GMBH, certificate number Q5 099188 0004 Rev. 04.
- Availability of technical documentation per Annex II and Annex III of the Medical Device Regulation (EU) 2017/745

This Declaration of Conformity is also issued on the basis of fulfilment the requirements of the Personal Protective Equipment Regulation (EU) 2016/425 for Category III (Module D):

• The conformity to type based on quality assurance of the production process under surveillance of the notified body number 2777 by SATRA Technology Europe Ltd.

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List of Applicable Regulations and Standards

No.	Regulation/ Standard	Regulation/ Standard Name
	Number	
1	MDR (EU) 2017/745	Medical Device Regulation
2	PPE (EU) 2016/425	Personal Protective Equipment Regulation
3	ISO 13485: 2016	Medical devices - Quality management
		systems - Requirements for regulatory
		purposes
4	ISO 9001: 2015	Quality management systems – requirements
5	ISO 14971: 2019	Medical devices - application of risk
		management to medical devices
6	EN 455-1: 2020	Requirements and testing for freedom from
		holes
7	EN 455-2: 2015	Requirements and testing for physical
		properties
8	EN 455-3: 2015	Requirements and testing for biological
		evaluation
9	EN 455-4 : 2009	Requirements and testing for shelf life
		determination
10	ISO 10993-1: 2018	Biological evaluation of medical devices –
		Part 1: Evaluation and testing within a risk
		management process
11	ISO 10993-5: 2009	Biological evaluation of medical devices –
		Part 5: Test for in vitro cytotoxicity
12	ISO 10993-10: 2010	Biological evaluation of medical devices –
		Part 10: Test for irritation and skin
		sensitization
13	ASTM F1671: 2013	Standard test method for resistance of
		materials used in protective clothing to

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ເບອຣ໌ແฟ็กซ์: 074-344-667, 074-237-423, 074-237-832



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for chemical risks		2018	chemicals and micro-organisms - Part 1:
			Terminology and performance requirements
21 EN ISO 371-2: 2019 Protective gloves against dangerous			for chemical risks
21 LINISC 574-2. 2019 Trotective gloves against dangerous	21	EN ISO 374-2: 2019	Protective gloves against dangerous
chemicals and micro-organisms - Part 2:			chemicals and micro-organisms - Part 2:
Determination of resistance to penetration			Determination of resistance to penetration
22 EN ISO 374-4: 2019 Protective gloves against chemicals and	22	EN ISO 374-4: 2019	Protective gloves against chemicals and
micro-organisms - Part 4: Determination of			micro-organisms - Part 4: Determination of
resistance to degradation by chemicals			resistance to degradation by chemicals

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No.	Regulation/ Standard Number	Regulation/ Standard Name
23	EN ISO 374-5: 2016	Protective gloves against dangerous
		chemicals and micro-organisms - Part 5:
		Terminology and performance requirements
		for micro-organisms risks
24	EN 16523-1: 2015+A1:	Determination of material resistance to
	2018	permeation by chemicals - Part 1: Permeation
		by liquid chemical under conditions of
		continuous contact



Name: Ms. Sureerat Choosri Position: Product Manager (Glove) Date: 15 June 2021 DoC expires after 5 years

Place of issue of the EU Declaration of Conformity: Sri Trang Gloves (Thailand) Public Company Limited 10 Soi 10, Phetkasem Road, Hat Yai, Songkhla 90110 Thailand